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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,819	06/21/2006	Go Watanabe	49288.1500	1793
20322 7590 07/27/2010 SNELL & WILMER LLLP. (Main) 400 EAST VAN BUREN ONE ARIZONA CENTER PHOENIX. AZ 85004-2202			EXAMINER	
			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
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			MAIL DATE	DELIVERY MODE
			07/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/550.819 WATANABE ET AL. Office Action Summary Examiner Art Unit SARAH WEBB 3731 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 08 July 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3.5-7.9.10.12-14 and 18-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-3,5-7,9,10,12-14 and 18-26 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/SB/06)

Attachment(s)

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

#### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/2010 has been entered.

## Claim Objections

Claims 24-26 are objected to because of the following informalities: the
requirement that the "recessed portion" is "raised" is confusing, since a recess normally
implies aperture or indentation in a surface. Appropriate correction is required.

## Response to Arguments

3. Applicant's arguments filed 6/11/2010 have been fully considered but they are not persuasive. Applicant's arguments were addressed in the Advisory Action mailed 6/28/2010. For clarification, the previously presented amendments and the new claims 21-23 simply add functional language that fails to further define the <u>structural characteristics</u> of the claimed invention over the prior art. Applicant argues that the Kees device does not teach a grasping member "for grasping a tubular tissue", but this language is directed only towards the intended use of the device. A recitation of the

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intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is *capable of* performing the intended use, then it meets the claim. In this case, Kees does disclose the ability of the device of the device to grasp a portion of a tubular tissue (12), as illustrated in Figure 1.

Applicant argues that Kees fails to disclose that the first grasping plate includes an edge portion which defines a shape of the opening, the end portion of the edge portion being inserted into a tube of the tubular tissue. First, Kees meets the **structural** requirements of a first grasping plate with an edge portion which defines a shape of the opening, where the end of the edge portion (labeled as elongated end portion in the figure provided below) is *capable* of being inserted into a tubular tissue. The language "elongated end portion" is significantly broad enough to encompass the scallop closest to slot (36), as stated in the previous rejections. Applicant has failed to specifically point out the **structural** differences between the claimed device and the Kees device, but merely asserts that Kees is not *capable* of being inserted into a tubular tissue..." is another recitation of intended use that is not given patentable weight. Since the device is *capable* of being inserted into a tubular tissue is clearly disclosed, the Kees device is considered to meet the claim limitations.

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

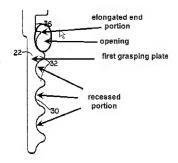
 Claims 1, 5-7, 9,10, 12-14, and 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kees, Jr. et al. (US 4,340,061).

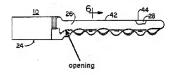
Regarding claims 1 and 6, Kees, Jr. et al. disclose a surgical holder comprising a grasping member (20, 22) for grasping a tissue, a manipulation member (24) for manipulating the grasping member (20, 22), and a connection portion (see figure below) with one end connected to the manipulation member, wherein: the grasping member includes a first grasping plate (22), and a second grasping plate (20) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other; the first grasping plate includes a retaining portion having an opening (see figure below) of a U- shape or substantially a U-shape which is opened toward an outer side of the first grasping plate and a supporting portion having a recessed portion (rounded scallops 30 of first grasping plate 22; see figure below), the opening being provided in one end of the first grasping plate and the recessed portion being provided in the other end of the first grasping plate, the first grasping plate includes an edge portion which defines the shape of the opening, the end portion (see figure below) of the edge portion being capable of being inserted into a tube of tubular tissue, the second grasping plate includes a covering portion (see figure

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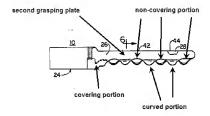
below) formed so as to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion (rounded scallops 30 of second grasping plate 20; see figure labeled below) which does not cover the first grasping plate, and a fixing portion having a curved portion (see figure below), the covering portion being provided in one end of the second grasping plate and the curved portion being provided in the other end of the second grasping plate, the curved portion opposing the recessed portion to form the tissue grasping space when the first grasping plate and the second grasping plate are positioned so as to oppose on another (Fig. 1), a first grasping portion which can grasp a part of a tissue between the opening of first grasping plate and the covering portion of the second grasping plate is provided in one end portion of the grasping member, and the opening exposing another part of the tissue when the part of the tissue is grasped by the first grasping portion; and a second grasping portion which can form a tissue grasping space between the recessed portion of the first grasping plate and the curved portion of the second grasping plate provided in another end portion of the grasping member.

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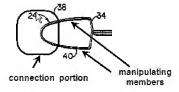
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Regarding claim 5. Kees, Jr. et al. disclose surgical holder comprising a grasping member (20,22) for grasping a tissue, a manipulation member (see figure below) for manipulating the grasping member, and a connection portion (see figure below) with one end connected to the manipulation member and the other end provided with a fixing tool (clip handling tool, col. 2, In. 26-28), wherein: the grasping member includes a first grasping plate (22), and a second grasping plate (20) provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other; the grasping member is formed into a rectangular shape with the manipulation member elongated from a side thereof (Fig. 3-4); a first grasping portion which can grasp a part of a tissue between the first grasping plate and the second grasping plate, and an opening (see figure above), provided in the vicinity of the first grasping portion and exposing another part of the tissue, is provided in one end portion of the grasping member, the opening being opened at an outer side of the first grasping portion; the first grasping plate includes an edge portion which defines the shape of the opening, the end portion of the edge portion being capable of

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being inserted into a tube of tubular tissue, and a second grasping portion which can form a tissue grasping space between the first grasping plate and the second grasping plate (between curved and recessed portions labeled above) provided in another end portion of the grasping member, the tissue grasping space and the opening being positioned at respective ends on one axis of the grasping member.



Regarding claim 7, the device of Kees, Jr. et al. is capable of grasping a tubular tissue with a surrounding tissue, and the part which defines the shape of the opening of the first grasping plate and the covering portion of the second gasping plate is capable of grasping the surrounding tissue.

Regarding claim 9, the device of Kees, Jr. et al. is capable of grasping a tubular tissue, and the retaining portion of the first grasping plate and the covering portion of the second gasping plate is capable of grasping the tubular tissue at one point of the tubular tissue and a tissue grasping space formed by the recessed portion of the first grasping

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plate and the curved portion of the second grasping plate is capable of grasping another point of the tubular tissue.

Regarding claim 10, the device of Kees, Jr. et al. is capable of grasping a tubular tissue by inserting the edge portion into a tube of the tubular tissue.

Regarding claims 12-14, the recessed portion is provided toward a thickness of the first grasping plate.

Regarding claims 18-20, Kees, Jr. et al. disclose the first and second grasping plates of flat plate shape (Figure 3), the curved portion is provides on a fixing portion which is provided to extend from the covering portion through an elongated piece (see figure above), and the opening of a rectangular shape is formed by an edge (34) of the covering portion, the elongated piece, and the fixing portion (Fig. 2).

Regarding claims 21-23, these claims fail to further define the structural characteristics of the invention and are only directed towards the intended use of the device. Therefore, they are not given patentable weight.

Regarding claims 24-26, a "recessed portion" as pointed out above in the figures forms a "generally tubular tissue grasping space." Since the claim does not define in which direction the recessed portion is "raised", the recessed portions pointed out above could be described as "raised" from the outer edge of the plate. The claim language is significantly broad enough to encompass this structure, because no axis or plane is defined for clarity of the relative terminology.

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### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

 Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees, Jr. et al. (US 4,340,061) in view of Mandel et al. (US 2002/0177863).

Regarding claims 2 and 3, Kees fails to disclose a tissue protection material is attached to an opposing surface of the first grasping plate and/or the second grasping plate, wherein the tissue protection material is permeated with medicines. Mandel et al. disclose providing an antimicrobial and/or antibiotic coating to the surfaces of a ligating clip in order to prevent and kill microorganisms in the area of the clip (paragraphs 33 and 34). It would have been obvious to one of ordinary skill in the art to modify the clip of Kees, Jr. et al to include a tissue protecting coating containing antibiotic or antimicrobial materials or medicines in order to prevent growth and to kill microorganisms in the area of the clip.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH WEBB/ Examiner, Art Unit 3731

/Anhtuan T. Nguyen/ Supervisory Patent Examiner, Art Unit 3731 7/24/10